



[7590-01-P]

NUCLEAR REGULATORY COMMISSION

In the Matter of

Bradley D. Bastow, D. O.
South Haven, Michigan

)
)
)
)

[Docket No. 030-35710]
[License No. 21-32316-01]
[EA-13-025]

[NRC-2013-0208]

Confirmatory Order Modifying License

I

Bradley D. Bastow, D. O., (Dr. Bastow or the licensee) is the holder of Materials License No. 21-32316-01 issued by the U.S. Nuclear Regulatory Commission (NRC) pursuant to part 30 of Title 10 of the Code of Federal Regulations (10 CFR part 30) on April 20, 2001, and renewed on December 7, 2011. The license authorizes the operation of Bradley D. Bastow, D. O., at his place of business (Cardiology II, P.C.) (facility) in accordance with conditions specified therein. The facility is located on the licensee's site in South Haven, Michigan.

This Confirmatory Order is the result of an agreement reached during an alternative dispute resolution (ADR) mediation session conducted on July 1, 2013.

II

On February 28, and April 3, 2012, the NRC conducted a special inspection at the Bradley D. Bastow, D. O., facility in South Haven, Michigan, with continued in-office review through May 24, 2012. The details of the inspection were documented in NRC Inspection Report No. 03035710/2012001(DNMS) issued on December 19, 2012. During the inspection, several unresolved items were identified that required further NRC review. The NRC Office of

Investigations (OI) began an investigation on April 2, 2012 into several of the issues. OI completed its investigation on January 31, 2013.

During the inspection and investigation, the NRC determined that Bradley D. Bastow, D. O., was in apparent violation of NRC requirements by: (1) failing to perform weekly contamination surveys; (2) failing to perform storage area surveys; (3) failing to conduct a survey instrument calibration; (4) failing to monitor the external surfaces of labeled packages for radioactive contamination; (5) failing to conduct dose calibrator linearity tests that were calibrated with nationally recognized standards; (6) failing to conduct a formal annual review of the radiation safety program; (7) failing to ensure that records were complete and accurate; (8) failing to issue a whole body radiation exposure measuring device to an individual who was occupationally exposed to ionizing photon radiation on a regular basis and failing to issue a finger radiation exposure measuring device to an individual who handled radioactive material on a regular basis; (9) failing to read film badges on a monthly basis, and the named Radiation Safety Officer (RSO) failing to evaluate the results; (10) failing to leak test sealed sources at 6 months intervals; (11) failing to conduct a semi-annual physical inventory of all sealed sources in its possession; (12) failing to perform daily surveys; (13) failing to assay wipes for removable contamination using a procedure sufficiently sensitive to detect 2000 disintegrations per minute (dpm); and (14) the named RSO failing to ensure that radiation safety activities were being performed in accordance with licensee-approved procedures and regulatory requirements.

On July 1, 2013, Bradley D. Bastow, D. O., and the NRC met in an ADR session mediated by a professional mediator, arranged through Cornell University's Institute on Conflict Resolution. ADR is a process in which a neutral mediator with no decision-making authority assists the parties in reaching an agreement on resolving any differences regarding the dispute. This confirmatory order is issued pursuant to the agreement reached during the ADR process.

III

In response to the NRC's offer, Bradley D. Bastow, D. O., requested use of the NRC ADR process to resolve differences it had with the NRC. During that ADR session, a preliminary settlement agreement was reached. The elements of the agreement consisted of the following:

A. Restoring Compliance:

- A.1. The NRC will issue a written Notice of Violation to accompany the Order addressing the violations and the licensee will respond with how the violations were corrected, within 30 days of the date of the Order. The NRC agrees to group the violations to reduce the total number such that all the completeness and accuracy violations are discussed in one violation and all the survey violations are discussed in a second violation.
- A.2. Within 30 days of the date of the Order, the licensee will ensure that all equipment listed on the license (except the well counter) is restored to service, calibrated, and operable, including a back-up survey meter. In the case of the well counter, the licensee will either restore a well counter to service (calibrated and operable) or will provide a license amendment request for alternate instrumentation within 60 days of the date of the Order.

B. RSO responsibilities and involvement:

- B.1 Within 90 days of the date of the Order, Dr. Bastow will complete a medical RSO refresher training class (approximately 8 hours).
- B.2 Within 60 days of completion of the RSO training identified in B.1, Dr. Bastow will meet with and “shadow” for at least 8 hours another RSO who oversees a nuclear medical program. The licensee will retain documentation showing the name of the RSO whom he shadowed, contact information, approximate hours spent and insights gained. If Dr. Bastow is unable to shadow another RSO, then the licensee will document the names and contact information for three individuals whom he contacted, the dates of contact and the reasons they provided for not allowing him to shadow them.
- B.3 Upon issuance of the Order, the licensee will increase radiation safety program reviews from annually to quarterly for one year and provide a copy of the reports to the NRC within 60 days of completion of the audits. The reports must include all documented safety concerns raised by persons (staff and contractors) performing duties under the NRC license, along with any self-identified violations and the corrective actions taken to resolve the concerns. After the first year, the licensee will provide its annual written report to the NRC for the next three years. The reviews will be conducted by an independent consultant under contract with the licensee. The licensee must provide written certification that he has reviewed the report and agrees with the results of the review along with independent observations that he has made of the health of the radiation safety program; the

licensee will also implement actions recommended in the report or document justification for not implementing the recommended actions.

C. Safety Culture:

- C.1. Within 30 days of the date of the Order, the licensee will document a written Safety Culture Policy that applies to all persons (staff and contractors) performing duties under the NRC license. The policy must include that concerns will be documented, the actions taken to resolve the concerns, who resolved the concern, and when the concern was resolved. Upon resolution of the concern, the documented concern is signed by both the concerned individual and the RSO that resolution was satisfactory. If the concern cannot be resolved, the documented concern should state why the concern cannot be resolved and the concerned individual understands why the concern cannot be resolved. The Safety Culture Policy must iterate that any concerned individual can contact the NRC (provide phone number and contact person at NRC) for additional action on nuclear safety issues if necessary. The licensee shall provide a copy of the policy to all persons (staff and contractors) performing duties under the NRC license and conspicuously post the policy or a notice about the policy in the licensee's office in several locations.
- C.2. Within 60 days of the date of the Order, the RSO will provide initial training to the staff and contractors performing duties under the NRC license regarding safety culture and raising safety concerns. For the next two years, the RSO will provide annual refresher training. The RSO will provide training to any new staff or contractors performing duties under the NRC license within 30 days of their

arrival. Documentation of the training will be maintained for future inspection, including the dates of the training, the names of the attendees, and the subjects covered.

- C.3. Once a quarter beginning within 60 days of the date of the Order, the licensee will meet with each person (staff and contractors) performing duties under the NRC license to solicit concerns and will document any concerns and the actions taken to address them. This shall continue for at least three years. The results shall be documented in the quarterly or annual audit.

D. Accuracy and Completeness of Records:

- D.1 Within 90 days of the date of the Order, the licensee will review its records for 2012 and 2013 against NRC requirements and license commitments. The licensee will verify that all required records (including all records and documents created in support of such records) are onsite and are available for inspection. Furthermore, the licensee shall ensure that any supporting worksheets are clearly attached. The licensee shall ensure all documentation is complete, accurate, clear, and legible and information is easily traceable from one form to another without question. For example, survey instrumentation shall clearly indicate model and serial numbers. If forms or documents contain signature blocks, the name of the signee will be printed or typed on the form and will include a date signed. This review shall be completed within 90 days of the date of the Order. Any discrepancies will be documented and the NRC informed within the following 30 days.

D.2 The NRC agrees to waive any additional enforcement action for any additional examples of the violations described above identified as a result of the reconciliation effort identified in D.1.

E. Notification of Completion of Activities:

Unless otherwise specified, the licensee will submit written notification to:

U.S. NRC Region III
Director, Division of Nuclear Material Safety
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

upon completion of each specific action at six months, one year, and annually thereafter until total completion.

F. The resulting Confirmatory Order will be considered an escalated enforcement action by the NRC for any future assessment of Bradley D. Bastow, D. O., as appropriate.

G. In consideration of the commitments above, the NRC agrees to a civil penalty in the amount of \$1,000 and to take no further enforcement action in the matter of EA-13-025 discussed in the NRC's letter to Dr. Bastow dated April 18, 2013.

On August 22, 2013, Bradley D. Bastow, D. O., consented to issuing this Order with the commitments, as described in Section V below. Bradley D. Bastow, D. O., further agreed that

this Order is to be effective upon issuance and that the licensee has waived its right to a hearing.

IV

Since the licensee has agreed to take additional actions to address NRC concerns, as set forth in Item III above, the NRC has concluded that its concerns can be resolved through issuance of this Confirmatory Order.

I find that Bradley D. Bastow, D. O.'s commitments as set forth in Section V are acceptable and necessary and conclude that with these commitments the public health and safety are reasonably assured. In view of the foregoing, I have determined that public health and safety require that Bradley D. Bastow, D. O.'s commitments be confirmed by this Order. Based on the above and Bradley D. Bastow, D. O.'s consent, this Confirmatory Order is effective upon issuance.

V

Accordingly, pursuant to Sections 81, 161b, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR part 30, IT IS HEREBY ORDERED, THAT LICENSE NO. 21-32316-01 IS MODIFIED AS FOLLOWS:

A. Restoring Compliance:

- A.1. Within 30 days of the date of the Order, the licensee will respond with how the violations enclosed with the Order were corrected.

A.2. Within 30 days of the date of the Order, the licensee will ensure that all equipment listed on the license (except the well counter) is restored to service, calibrated, and operable, including a back-up survey meter. In the case of the well counter, the licensee will either restore a well counter to service (calibrated and operable) or will provide a license amendment request for alternate instrumentation within 60 days of the date of the Order.

B. RSO responsibilities and involvement:

B.1 Within 90 days of the date of the Order, Dr. Bastow will complete a medical RSO refresher training class (approximately 8 hours).

B.2. Within 60 days of completion of the RSO training identified in B.1, Dr. Bastow will meet with and “shadow” for at least 8 hours another RSO who oversees a nuclear medical program. The licensee will retain documentation showing the name of the RSO whom he shadowed, contact information, approximate hours spent and insights gained. If Dr. Bastow is unable to shadow another RSO, then the licensee will document the names and contact information for three individuals whom he contacted, the dates of contact, and the reasons they provided for not allowing him to shadow them.

B.3. Upon issuance of the Order, the licensee will increase radiation safety program reviews from annually to quarterly for one year, and provide a copy of the reports to the NRC within 60 days of completion of the reviews. The reports must include all documented safety concerns raised by persons (staff and contractors)

performing duties under the NRC license, along with any self-identified violations and the corrective actions taken to resolve the concerns. After the first year, the licensee will provide its annual written report to the NRC for the next three years. The reviews will be conducted by an independent consultant under contract with the licensee. The licensee must provide written certification that he has reviewed the report and agrees with the results of the review along with independent observations that he has made of the health of the radiation safety program; the licensee will also implement actions recommended in the report or document justification for not implementing the recommended actions.

C. Safety Culture:

- C.1. Within 30 days of the date of the Order, the licensee will document a written Safety Culture Policy that applies to all persons (staff and contractors) performing duties under the NRC license. The policy must include that all concerns will be documented, the actions to be taken by the licensee to resolve the concerns, which individual will be responsible for the resolution of the concerns, and the expected timeframe in which the concern will be resolved. Upon resolution of the concern, the documented concern is signed by both the concerned individual and the RSO that resolution was satisfactory. If the concern cannot be resolved, the documented concern should state why the concern cannot be resolved and that the concerned individual understands why the concern cannot be resolved. The Safety Culture Policy must iterate that any concerned individual can contact the NRC (provide phone number and contact person at NRC) for additional action on nuclear safety issues if necessary. The licensee shall provide a copy of the policy to all persons (staff and contractors) performing duties under the NRC

license and conspicuously post the policy or a notice about the policy in the licensee's office in at least two locations.

C.2. Within 60 days of the date of the Order, the RSO will provide initial training to the staff and contractors performing duties under the NRC license regarding safety culture and raising safety concerns. For the next two years, the RSO will provide annual refresher training. The RSO will provide training to any new staff or contractors performing duties under the NRC license within 30 days of their arrival. Documentation of the training will be maintained for future inspection, including the dates of the training, the names of the attendees, and the subjects covered.

C.3. Once a quarter beginning within 60 days of the date of the Order, the licensee will meet with each person (staff and contractors) performing duties under the NRC license to solicit concerns and will document any concerns and the actions taken to address them. This shall continue for at least three years. The results shall be documented in the quarterly or annual audit.

D. Accuracy and Completeness of Records:

D.1 Within 90 days of the date of the Order, the licensee will review its records for 2012 and 2013 against NRC requirements and license commitments. The licensee will verify that all required records (including all records and documents created in support of such records) are onsite and are available for inspection. Furthermore, the licensee shall ensure that any supporting worksheets are clearly attached. This review shall be completed within 90 days of the date of the

Order. Any discrepancies will be documented and the NRC informed within the following 30 days.

The licensee shall ensure all documentation completed following issuance of the Order is complete, accurate, clear, and legible. For example, survey instrumentation shall clearly indicate model and serial numbers. If forms or documents contain signature blocks, the name of the signee will be printed or typed on the form and will include a date signed.

E. Notification of Completion of Activities:

Unless otherwise specified, the licensee will submit written notification to:

U.S. NRC Region III
Director, Division of Nuclear Material Safety
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

upon completion of each specific action at six months, one year, and annually thereafter until total completion.

F. Within 30 days of the date of the Order, the licensee shall pay the civil penalty in the amount of \$1,000 in accordance with NUREG/BR-0254 and submit to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, a statement indicating when and by what method payment was made.

The Regional Administrator, Region III, may, in writing, relax or rescind any of the above conditions upon demonstration by Bradley D. Bastow, D. O., of good cause.

VI

Any person adversely affected by this Confirmatory Order, other than Bradley D. Bastow, D. O., may request a hearing within 20 days of its publication in the Federal Register. Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time must be made in writing to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and include a statement of good cause for the extension.

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC E-Filing rule (72 FR 49139, August 28, 2007). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least ten (10) days prior to the filing deadline, the participant should contact the Office of the Secretary by e-mail at hearing.docket@nrc.gov, or by telephone at 301-415-1677, to request: (1) a digital ID certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an

NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals/apply-certificates.html>. System requirements for accessing the E-Submittal server are detailed in NRC's "Guidance for Electronic Submission," which is available on the agency's public Web site at <http://www.nrc.gov/site-help/e-submittals.html>. Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through the Electronic Information Exchange (EIE), users will be required to install a Web browser plug-in from the NRC Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals.html>.

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC public Web site at <http://www.nrc.gov/site-help/e-submittals.html>. A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the

document to the NRC Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the agency's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk through the "Contact Us" link located on the NRC Web site at <http://www.nrc.gov/site-help/e-submittals.html>, by email at MSHD.Resource@nrc.gov, or by a toll-free call at 866-672-7640. The NRC Meta System Help Desk is available between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) first class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in NRC's electronic hearing docket which is available to the public at <http://ehd1.nrc.gov/ehd/>, unless excluded pursuant to an order of the Commission, or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

If a person other than the licensee requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Confirmatory Order and shall address the criteria set forth in 10 CFR 2.309(d) and (f).

If a hearing is requested by a person whose interest is adversely affected, the Commission will issue an order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Confirmatory Order should be sustained.

In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, the provisions specified in Section V above shall be final 20 days from the date this Confirmatory Order is published in the Federal Register without further order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions specified in Section V shall be final when the extension expires if a hearing request has not been received.

A REQUEST FOR HEARING SHALL NOT STAY THE EFFECTIVENESS OF THIS ORDER.

FOR THE NUCLEAR REGULATORY
COMMISSION

Cynthia D. Pederson,
Regional Administrator,
Region III.

Dated this 3rd day of September 2013.

[FR Doc. 2013-22315 Filed 09/12/2013 at 8:45 am; Publication Date: 09/13/2013]

